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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,387	05/06/2002	Robert J Beynon	39-254	2329

7590 07/15/2004

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Arlington, VA 22201-4714

EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,387	BEYNON ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 6, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence letter*.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Claim one recites a method for detecting for the presence of urinary proteins from rodents on a surface, but the method does not include essential steps such as contact, binding and detection.

4. Claims 14 recites the limitation "and functional derivatives thereof" is vague because it is unclear as to what is encompassed by this term. The specification does not give a clear definition and clarification is needed.

5. Claim 14 recites "a protein amino acid sequence as defined by Genbank Accession Numbers". It is unclear as to what is being claimed. It appears that applicant is claiming a sequence by its individual accession. If this is the case, a SEQ I.D. Numbers are required along with a sequence listing.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is dependent is drawn to a major urinary protein that has an amino acid sequence as defined as defined by Genbank Accession numbers X00907, M16355, M16356 or Xoo908 and functional derivatives thereof. The written description in this case only sets forth specific major urinary proteins, therefore the written description is not commensurate in scope with the claims drawn to functional derivatives thereof. Neither the specification nor the claims teach how to define derivatives thereof. Neither the claims nor the specification teach how to obtain such functional derivatives thereof. There is no guidance as to what the functional derivatives are; or what derivatives can or cannot be used in the instant invention being claimed. There is no disclosure of what portions of derivatives are functional; neither is there disclosure of how to determine the functional derivatives of the amino acid sequence concerning urinary proteins.

There specification fails to teach how to obtain these functional derivatives or describe an assay that could elucidate the functional portions. The specification does not include structural examples of functional derivatives thereof. Thus, the resulting derivatives could result in a major urinary protein or functional derivatives thereof not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (*See Vas-Cath* at page 1117).

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). With the exception of specifically named derivatives the skilled artisan cannot envision the detailed structure of the functional derivatives thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of functional derivatives thereof falling within the scope claims. Therefore only the recited claim 14 fail to meet the full breadth of the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 12-13, 15 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Chapman et al (USP#5,869,288).

The claims are broadly drawn to a method of determining the presence of rodent infestation by detecting for urinary proteins from rodents. Chapman et al teaches that calycins are a set of diverse protein families that contain rodent urinary proteins (mouse urinary protein, MUP, and rat alpha 2u globulin). These rodent urinary proteins induce IgE antibody responses as they become airborne when deposited on particles in laboratory animal rooms or houses containing rats (column 10, lines 16-24).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al (USP#5,869,288) in view of Robertson et al (Journal of Biochemistry, 1996, Vol. 316, pages 265-272).

The teachings of Chapman et al are set forth above but is silent with respect to the amino acid sequence of major urinary proteins as defined by Genbank Accession Numbers.

However, Robertson et al discloses a table that includes a proposed classification and nomenclature for uMUPs that are listed by their Genbank accession numbers X00907, M16355, M16356, and X00908.

It would have been obvious to one of ordinary skill in the art to modify the teachings of Chapman et al to include the identification of major urinary proteins by their amino acid sequences to distinguish them one from the other. One of ordinary skill in the art would be motivated to do so because all major urinary proteins are not the same and therefore they are very specific to its individual antibody.

12. Claim 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al (USP#5,869,288) in view of Bayard et al (Electrophoresis 1998, Vol. 189, pages 1642-1648).

The teachings of Chapman et al are set forth above and differ from the instant claims in not teaching an immunoassay system associated with a double antibody system.

However, Bayard et al teaches rat urinary proteins binding human IgE antibodies (introduction, column 2). Bayard et al also teaches the affinity and specificity of IgE antibodies utilizing a double antibody system, particularly a dot blot with concentrated rat urine. Bayard discloses detection of IgE rat antigens with anti-IgE (secondary antibodies) antibodies are important because low detection signals could be the result of IgE antibodies (primary antibodies) that can be lost during washing of the membrane due to weak binding (page 1646, column 2, paragraph 3-4 and page 1647, column 2, paragraph 1).

It would have been obvious to one of ordinary skill in the art to modify the reference of Chapman et al to include a double antibody system to detect the degree of affinity of the IgE antibodies to rat urinary proteins. Further, a double antibody system is well known in the art of its detection sensitivity.

13. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al (USP#5,869,288) in view of Bayard et al (Electrophoresis 1998, Vol. 189, pages 1642-1648 and further in view of Patrick Yamanton (USP#5,359,960).

The teachings of Chapman et al in view of Bayard et al are set forth above and differ from the instant claims in not teaching a system to collect urine samples.

However, Patrick Yamanton teaches a diagnostic system for use with small animals consisting of using plastic liners (sheets or substratum) to collect urine from animal deposits. The urine sample is transferred to a dipstick (swab) for testing of the analyte (column 5, lines 59-68 and column, lines 1-20). Yamanton teaches an

alternative to using dipsticks would be the use of paper impregnated with phenol red, that when the urine passes from the animal to the paper, immediate results are present (column 12, lines 1-25).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Chapman et al in view of Bayard et al to utilize a urine collection system taught by Yamanton to include to provide simple home testing of animals without the use of a laboratory and the need of trained technicians. The skilled artisan would be motivated to include this teaching because it provides for quick and easy testing of analytes in urine samples of small animals. With respect to a material being nitrocellulose, this is well known material in the art used for sample collection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Held et al. (Biochemical Genetics, Vol. 23, Nos. 3 & 4, 1985, pages 281-290) teaches rat α2u-Globulin mRNA expression in urine.

B. Robertson e al (Journal of Biochemistry, 1996, vol. 316, pages 265-272) teaches major urinary proteins of the house mouse Mus musculus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
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June 10, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

07/12/04

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
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APPLICATION NO. /CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/031,387	5-6-2002	Beynon et al	39-254

EXAMINER	
Deborah A. Davis	
ART UNIT	**PAPER**
1641	

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN THREE MONTHS FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:
1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)
2. Mailed to:
U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examine Jacob Cheu whose telephone number is (571) 272-0814.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Long Le. (571-272-0823)

Notice to Comply	Application No. 10/031,387	Applicant(s) Beynon et al
	Examiner Deborah A. Davis	Art Unit 1641

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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